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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/391,762 09/08/99 WEADOCK

K 498-36-RES

EXAMINER

QM12/0726

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PREBILIC P

ART UNIT

PAPER NUMBER

3738

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.

09/391,762

Applicant(s)

Weadock et al

Examiner

Paul Prebilio

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 14, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 8 20) ☐ Other:

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The original patent, or an affidavit or declaration as to loss or inaccessibility of the original patent, must be received before this reissue application can be allowed. See 37 CFR 1.178.

The Examiner has considered the information disclosure statement except for EP 0237037 because it or relevant portions thereof were not translated in English.

Claims 13-18 are rejected under 35 U.S.C. 251 as being an improper recapture of broadened claimed subject matter surrendered in the application for the patent upon which the present reissue is based. See *Hester Industries, Inc. v. Stein, Inc.*, 142 F.3d 1472, 46 USPQ2d 1641 (Fed. Cir. 1998); *In re Clement*, 131 F.3d 1464, 45 USPQ2d 1161 (Fed. Cir. 1997); *Ball Corp. v. United States*, 729 F.2d 1429, 1436, 221 USPQ 289, 295 (Fed. Cir. 1984). A broadening aspect is present in the reissue which was not present in the application for patent. The record of the application for the patent shows that the broadening aspect (in the reissue) relates to subject matter that applicant previously surrendered during the prosecution of the application. Accordingly, the narrow scope of the claims in the patent was not an error within the meaning of 35 U.S.C. 251, and the broader scope surrendered in the application for the patent cannot be recaptured by the filing of the present reissue application.

Present claims 13-18 are improper for a reissue application because they attempt to recapture subject matter surrendered in order to overcome a prior art rejection. Specifically, during the pendency of the patented file 08/289,790, the language "filled with fluid which solidifies and is crosslinked to form" and "said material being insoluble at a pH of about 7.4" was

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added in order to overcome a prior art rejection. Therefore, it is improper to attempt to recapture this subject matter via claims 13-18 in the present reissue application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 13 is rejected under 35 U.S.C. 102(e) as being anticipated by Jernberg (US 5,290,271), or alternatively under 35 U.S.C. 103(a) as being unpatentable over Jernberg (US 5,290,271) alone. Jernberg anticipates the claim language wherein the microparticles are the

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precipitated composition as claimed since they are precipitated out of a fluid suspension onto and into the expanded polytetrafluoroethylene substrate; see the entire document. Precipitation can be simply a removing of suspended solid particles out of liquid suspension of those particles, and thus, the claim language is fully met with this interpretation.

Alternatively, since the process limitations are not explicitly set forth in Jernberg, one could interpret the claim as not being fully met. However, since it appears that at least a substantially identical product is produced thereby, it is the Examiner's position that the claimed product is at least clearly obvious over Jernberg alone; see MPEP 2113 which is incorporated into this rejection by reference thereto.

Claims 1-8 and 11-18 are rejected under 35 U.S.C. 102(b) as anticipated by Tran et al (article entitled "Plasma Modification . . . ") or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tran et al (article entitled "Plasma Modification . . . ") in view of Okita (US 4,193,138). Tran et al (article) anticipates the claim language wherein GORTEX grafts are synonymous with expanded polytetrafluoroethylene grafts which have node and fibrils as claimed. The collagen is precipitated out of the Vitrogen solution as a suspension onto the graft substrate at a particular pH and temperature such that the crosslinking reaction can take place; see the entire document.

Alternatively, one may not consider Tran et al (article) an anticipating patent because it does not explicitly disclose the fibril and node structure as set forth in the present claims. However, the Okita teaches that such fibril and node structure is known to the same art and

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indirectly that GORTEX is an expanded polytetrafluoroethylene material with nodes and fibrils; see the entire document, especially the figures and column 1, lines 26-41. Hence, it is the Examiner's position that it would have been obvious to use the graft of Okita as the substrate of Tran et al for the same reasons that Okita uses the same in the invention thereof and so that an impregnatable substrate material can be used as a better means to hold the collagen to the graft.

With regard to claim 17, Applicant is directed to page 375, second column, lines 1-9 where phosphate buffer saline is used to maintain the pH close to 7.00 which is also "about 7.4" as claimed.

Claims 1-10, 13-16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoffman Jr. et al (US 5,197,977) in view of Okita et al (US 4,193,138). Hoffman Jr. et al meets the claim language by disclosing a vascular graft which is sealed by a precipitate of collagen and solidified by crosslinking but fails to disclose the expanded PTFE substrate as claimed; see the entire document. Okita, however, teaches that it was known to the art to use expanded PTFE as a substrate or implant material in order to provide an inert graft material; see the entire document. Hence, it is the Examiner's position that it would have been obvious to use the Okita base material or substrate as the substrate of Hoffman, Jr. et al so that the inert and advantageous properties envisioned by Okita can be utilized in the Hoffman, Jr. et al invention.

Claims 1-8, 11, 13-16, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alonso (US 5,037,377) in view of Okita (US 4,193,138). Alonso discloses many types of porous substrates for use therewith but fails to disclose the use of expanded PTFE, which

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inherently has the node and fibril structure recited in claims 1 and 13, as the substrate material; it is noted that soluble collagen of Alonso is made insoluble by crosslinking it and that it is insoluble at a 7.4 pH because 7.4 is the pH of the crosslinking solution and the crosslinking solution does not dissolve the collagen material; see the entire document. Okita, however, teaches that it was known to use expanded PTFE as a substrate and graft material in order to provide an inert graft material; see the entire document. Hence, it is the Examiner's position that it would have been obvious to use the Okita base material or substrate for the base or substrate of Alonso so that inert and advantageous properties envisioned by Okita can be utilized in the Alonso invention.

Response to Arguments

Applicant's arguments filed August 14, 2000 have been fully considered but they are not persuasive.

Applicant traverses the 35 USC 251 rejection by stating that recapture is permitted when the claim is narrowed so as to remove it from trying to obtain surrendered subject matter. Upon careful consideration of the Applicant's remarks and the file wrapper histories of the cases involved, the Examiner came to the conclusion that the recapture that Applicant is attempting is impermissible.

Since the present claims 13-18, which broaden the scope of the patented claims in some regard, were filed within 2 years of the patent date, Applicant is within the statute in attempting to

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broaden the claims. The broadening is based upon the scope of the claims granted in the patent; present claims 1-12 are of the same scope as the patented claims 1-12.

Applicant argues that the present claim 13 does not impermissibly recapture surrendered subject matter because claim 13 has been narrowed in some aspects such that it is sufficiently distinct from patented claim 1 so as to not claim the surrendered subject matter. However, the Examiner posits that the added limitations do not sufficiently distinguish it from the surrendered claim.

In particular, Applicant is directed to MPEP 1412.02 and Examples A and particularly B thereof which closely match the present fact scenario. In addition, Applicant is directed to review the interview summary record (Paper No. 17) of the patented file which states that **“Agreed on language that distinguishes over Jernberg and the other arts of record. Claim 1 has been amended to include allowable language.”** Examiner Brittingham’s summary of the interview was never contradicted or questioned by the Applicant upon receipt thereof and the application subsequently issued.

Along with the interview, three specific changes were made to claim 1 which put the claims in condition for allowance. The amendments to claim 1 on February 27, 1997 were as follows:

In claim 1, on line 6, the language ----filled with fluid which solidifies and is crosslinked to form---- was inserted after “pores” and the word “containing” was deleted on this same line.

In claim 1, on line 6, after “solid”, ---precipitate of a--- was inserted.

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In claim 1, on line 8, after “origin”, ----said material being insoluble at a pH of about 7.4---- was inserted.

It is the Examiner's position that claim 13, which is similar to patented claim 1 except that it is broader in some aspects and narrower in another, is attempting to eliminate or broaden these limitations without significantly or sufficiently limiting claim 13 in other aspects.

Applicant argues that claim 13 is broader in some aspects but narrower than patented claim 1 in other aspects. In response, the Examiner the present broadening, which (1) leaves out the pH value, (2) only substantially fills the pores with a solidified material, (3) does not claim that the composition is crosslinked, and (4) does not state that the composition is “solid”, is not acceptable because these limitations were relied upon to put the claims in allowable form.

In response to the Applicant's argument that the narrowing aspects of claim 13 remove it from a recapture scenario, the Examiner asserts that both temperature and cellular attachment are broad limitations as they are set forth. In particular, the temperature limitation is based upon a process of making condition in this product claim. For this reason, it is not significantly limiting. Furthermore, the cellular attachment limitation is a statement of intended use merely stating the purpose of the biodegradable composition. In other words, it is not clearly related to any particular structure of the composition. Furthermore, the pore filling limitation is actually broader than patented claim 1 because present claim 13 sets forth “substantially fills” instead of “fills”; see

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MPEP 2173.05(b) which is incorporated herein by reference. For this reason, the narrowing limitations are not considered significant.

In response to the traversal stating that the *Whittaker Corp. v. UNR Industries, Inc.* decision allowed reissue claims broader in certain aspects but narrower in others, the Examiner respectfully disagrees and takes the position that this case only decided one issue, that is, whether the reissue patent claims differ materially from the claims that were surrendered to obtain the original patent; see page 1744 of the decision. It is not seen, in this decision, where reissue claims can^{be} broadened and still avoid the recapture doctrine. Nonetheless, that is not the particular issue here where patentee clearly surrendered subject matter and is attempting to recapture that same subject matter in this reissue application.

Furthermore, there is additional evidence of record which suggests that recapture of surrendered subject matter is being attempted. Specifically, the reissue declarations filed November 26, 1999 state that the purpose of the reissue was to broaden the pH limitation. Since the pH value was added to overcome a ground of rejection, the broadening of it at this point is considered to result in recapture.

In response to the traversal of the Jernberg rejection that a precipitate within the pores at selected conditions for cellular attachment is not produced, the Examiner respectfully disagrees. Jernberg, as stated in the altered rejection, discloses that the microparticles, which are the precipitated composition as claimed, are precipitated out of a fluid suspension onto and into the expanded polytetrafluoroethylene substrate; see the entire document. Precipitation can be simply

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a removing of suspended solid particles out of liquid suspension of those particles, and thus, the claim language is fully met with this interpretation.

In addition, Jernberg's microparticles are placed within the pores and "substantially fill[s]" them to the extent this language can be given weight; see column 3, lines 44-60 where the particles are disclosed as being placed within the pores. Moreover, "substantially" is a broad term; see MPEP 2173.05(b) which is incorporated herein by reference thereto.

Furthermore, this process, to the extent it can be given weight in a product claim (see MPEP 2113), is done at a pH and temperature which allows it to be done. Thus, the claim language in that regard is met. In addition, since the graft with microparticles, would not prevent cellular attachment, it also would function to be a site for cellular attachment to the extent that this language can be given weight. For these reasons, claim 13 is fully met by Jernberg such that the rejection thereon is maintained.

In response to the argument that the Jernberg material is not insoluble as claimed, the Examiner notes that polymers, such as collagen, which are insoluble and biodegradable fully meet the claim language.

Applicant argues that Tran et al (article) does not disclose porous PTFE as claimed. However, the Examiner posits that GORTEX is a type of expanded PTFE because this tradename refers precisely to the expanded form of PTFE. If Applicant would like verification of this fact, the Examiner could provide a copy of US Patent 5,207,709 which describes GORTEX as expanded PTFE.

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In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In this regard, Applicant traverses Okita as having no biodegradable composition. However, Okita was used as a teaching reference for the substrate and not for its coating composition.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned problem is corrected.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 305-3580.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.



Paul Prebilic
Primary Examiner
Art Unit 3738